

Form PTO-1390
P21742.P01

U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICE

ATTORNEY'S DOCKET NUMBER

P21742

TRANSMITTAL LETTER TO THE UNITED STATES
DESIGNATED/ELECTED OFFICE (DO/EO/US)
CONCERNING A FILING UNDER 35 U.S.C. 371

U.S. APPLICATION NO. (If known, see 37 CFR 1.5)

09/980120

INTERNATIONAL APPLICATION NO.

PCT/FR00/01457

INTERNATIONAL FILING DATE

29 May 2000

PRIORITY DATE CLAIMED

02 June 1999

TITLE OF INVENTION

BREAST PROSTHESIS

APPLICANT(S) FOR DO/EO/US

Marie-Christine MISSANA and Arnaud ROCHEBILIERE

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information.

1. ☒ This is a FIRST submission of items concerning a filing under 35 U.S.C. 371.
2. ☐ This is a SECOND or SUBSEQUENT submission of items concerning a filing under 35 U.S.C. 371.
3. ☒ This is an express request to promptly begin national examination procedures (35 U.S.C. 371(f)).
4. ☒ The US has been elected by the expiration of 19 months from the priority date (PCT Article 31).
5. ☒ A copy of the International Application as filed (35 U.S.C. 371(c)(2))
 - a. ☒ is attached hereto (required only if not communicated by the International Bureau).
 - b. ☒ has been communicated by the International Bureau.
 - c. ☐ is not required, as the application was filed in the United States Receiving Office (RO/US).
6. ☒ An English language translation of the International Application as filed (35 U.S.C. 371 (c)(2)).
"With Executed Verification"
7. ☐ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3))
 - a. ☐ are attached hereto (required only if not communicated by the International Bureau).
 - b. ☐ have been communicated by the International Bureau.
 - c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
 - d. ☐ have not been made and will not be made.
8. ☐ An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3))
9. ☒ An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).
"Executed"
10. ☐ An English language translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (U.S.C. 371(c)(5)).

Items 11 to 16 below concern other document(s) or information included:

11. Assignee: _____
12. ☐ An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
13. ☐ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
14. ☒ A FIRST preliminary amendment.
☐ A SECOND or SUBSEQUENT preliminary amendment.
15. ☐ A substitute specification.
16. ☐ A change of power of attorney and/or address letter.
17. ☐ Figure of Drawing to be published _____
18. ☒ Other items or information:
Cover Sheet and International Application as published in French.
Executed SES Form.
PCT/IB/304(in French).
PCT/IB/308(in French).
PCT/ISA/210.
Claim of Priority.

U.S. APPLICATION NO. (If known, see 37 CFR 1.5) <div style="font-size: 2em; font-weight: bold; margin-left: 100px;">09/980120</div>	INTERNATIONAL APPLICATION NO. PCT/FR00/01457	ATTORNEY'S DOCKET NUMBER P21742
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19. The following fees are submitted:				CALCULATIONS	PTO USE ONLY
Basic National Fee (37 CFR 1.492(a)(1)-(5)): Search report has been prepared by the EPO or JPO. \$ 890.00 International preliminary examination fee paid to USPTO (37 CFR 1.482). \$ 710.00 No international preliminary examination fee paid to USPTO (37 CFR 1.482) but international search fee paid to USPTO(37 CFR 1.445(a)(2)). \$ 740.00 Neither international preliminary examination fee (37 CFR 1.482) nor international search fee (37 CFR 1.445(a)(2) paid to USPTO. \$1,040.00 International preliminary examination fee paid to USPTO (37 CFR 1.482) and all claims satisfied provisions of PCT Article 33(2)-(4). \$ 100.00 <div style="text-align: right;">ENTER APPROPRIATE BASIC FEE AMOUNT =</div>				<div style="border: 1px solid black; height: 150px; width: 100%;"></div>	
Surcharge of \$130.00 for furnishing the oath or declaration later than 20 30 months from the earliest claimed priority date (37 CFR 1.492(e)).				\$	
Claims	Number Filed	Number Extra	RATE		
Total Claims	21 - 20 =	1	X \$18.00	\$18.00	
Independent Claims	1 - 3 =	0	X \$84.00	\$0.00	
Multiple dependent claim(s) (if applicable)			+ \$280.00	\$0.00	
TOTAL OF ABOVE CALCULATIONS =				\$908.00	
<input checked="" type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. The fees indicated above are reduced by 1/2.				\$454.00	
SUBTOTAL =				\$454.00	
Processing fee of \$130.00 for furnishing the English translation later than 20 30 months from the earliest claimed priority date (37 CFR 1.492(f)).				+	
Extension of Time fee in the amount of \$					
TOTAL NATIONAL FEE =				\$454.00	
Fee for recording the enclosed assignment (37 CFR 1.21(h). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property				+	
TOTAL FEES ENCLOSED =				\$454.00	
				Amount to be refunded	\$
				Charged	\$


a. ☒ A check in the amount of \$454.00 to cover the above fees is enclosed.

b. Please charge my Deposit Account No. _____ in the amount of \$_____ to cover the above fees.

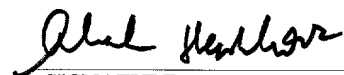
c. ☒ The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 19-0089.

NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the application to pending status.

SEND ALL CORRESPONDENCE TO CUSTOMER NO. 7055
 AT THE PRESENT ADDRESS OF:
 Neil F. Greenblum
 GREENBLUM & BERNSTEIN, P.L.C.
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07055


 SIGNATURE
 Neil F. Greenblum
 NAME
 28,394 45,294
 REGISTRATION NUMBER

PATENT TRADEMARK OFFICE

P21742.A01

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Marie-Christine MISSANA et al
Group Art Unit: Unknown
Serial No. : Not Yet Assigned
(U.S. National Phase of PCT/FR00/01457)
Examiner: Unknown
Filed : Concurrently Herewith
(I.A. Filed May 29, 2000)
For : BREAST PROSTHESIS

PRELIMINARY AMENDMENT

Commissioner of Patents and Trademarks
Washington, DC 20231

Prior to examination of the application and calculation of filing fees, please enter the following amendment.

IN THE SPECIFICATION

Please add the Abstract appended on a separate page as Appendix 1 at the end of this Amendment.

IN THE CLAIMS

Please amend claims 5-6, 8-10, 13, and 15-21 as follows (for the Examiner's convenience, a clean copy of all pending claims is being reproduced below, with amended claims 5-6, 8-10, 13, and 15-21 being so labeled, and a marked-up version of the amended claims being submitted in Appendix 2 attached at the end of this Amendment):

CLAIMS

1. Implantable breast prosthesis (1) comprising a soft pouch (2) capable of containing a filling material (3) such as a silicone gel or a physiological serum, characterized in that said prosthesis (1) is made side-specific, and in that the planes P7 and P8 tangent to the anterior surface (52) and to the posterior surface (51), respectively, of the pouch (2), once it is filled and in the implantation position at the inner edge (C), form an angle β less than 70° .

2. Prosthesis according to claim 1, characterized in that the side-specific arrangement of the prosthesis is obtained by an asymmetry of the pouch (2) in the implantation position, once it is filled, in relation to a plane P1 passing by the nipple (E) and the lower (D) and upper (B) front edges.

3. Prosthesis according to claim 2, characterized in that the asymmetry is defined by a difference in the dimensions between the projection EC of the distance between the nipple (E) and the front inner edge (C), on the one hand, and the projection EA of the distance between said nipple (E) and the front outer edge (A), on the other hand, along a plane P2 perpendicular to the plane P1 and containing the nipple (E) and the front upper edge B.

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4. Prosthesis according to claim 3, characterized in that the ratio $r(EC/EA)$ of said projections is less than or equal to 0.95, especially comprised between 0.8 and 0.9, or between 0.85 and 0.90, preferably equal to about 0.875.

5. (Amended) Prosthesis according to claim 3, characterized in that, along the plane P2, the dimension of the projection along the plane EC of the distance between the nipple (E) and the inner edge (C) and the dimension of the projection EA' of the distance between said nipple (E) and the rear outer edge A' are equal or very close.

6. (Amended) Prosthesis according to claim 3, characterized in that, along the plane P2, the dimension of the projection of the distance BE between the upper edge B and the nipple E is greater than the dimension of the projection of the distance ED between the nipple E and the lower edge D.

7. Prosthesis according to claim 6, characterized in that the ratio $r(BD/ED)$ is at least 1.1, especially between 1.1 and 2, and preferably between 1.3 and 1.5.

8. (Amended) Prosthesis according to claim 1, characterized in that, once filled and in the implantation position, the pouch (2) has an outer overlap (44) with respect to its

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posterior surface (51), extending especially between the lower (D) and the upper (B) posterior edges.

9. (Amended) Prosthesis according to claim 1, characterized in that the plane P5 tangent at the rear outer edge k to the anterior surface 52 forms, together with the plane P6 at said point k to the posterior surface 51, an obtuse angle ϕ , especially greater than 95 or 100°, especially comprised between 91° and 120°, for example on the order of 115°.

10. (Amended) Prosthesis according to claim 1, characterized in that the posterior surface (51) of the pouch (2) in the implantation position at least partially has at least one concave curvature.

11. Prosthesis according to claim 10, characterized in that the posterior surface (51) of the pouch (2) in the implantation position has a concave curvature in a horizontal plane P3 passing especially by the inner edge (C).

12. Prosthesis according to claim 11, characterized in that the projection GG' of the pole (G) of the posterior surface (51) along the concave curvature in a horizontal plane on the horizontal plane P4 containing the inner edge (C) and rear outer edge (A'), distance

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measured perpendicular to said plane, is at least 5 mm, especially at least 1 cm.

13. (Amended) Prosthesis according to claim 10, characterized in that the posterior surface (51) of the pouch (2) in the implantation position has a concave curvature in a vertical plane P9 passing especially by the upper edge (B).

14. Prosthesis according to claim 13, characterized in that the distance HH' between the pole (H) of the posterior surface (51) along the concave curvature in the vertical plane and the vertical plane P9 passing by the upper edge (B), distance measured perpendicular to said plane P9, is at least 1 mm, especially at least 2 mm, and preferably comprised between 3 and 6 mm.

15. (Amended) Prosthesis according to claim 1, characterized in that the projection of the distance HI between the pole H of the posterior surface (51) and the pole I of the anterior surface (52) along a vertical plane and passing by the upper B and lower D edges is comprised between 3 and 7 centimeters, and is here on the order of 5 centimeters.

16. (Amended) Prosthesis according to claim 1, characterized in that at least a portion of the posterior surface (51) of the pouch (2) is less deformable or more rigid than the

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remainder of the pouch (2), especially by selective thickening of said posterior surface.

17. (Amended) Prosthesis according to claim 1, characterized in that the planes P10 and P11 tangent to the posterior surface (51) and to the anterior surface (52), respectively, of the pouch (2), once it is filled and in the implantation position at the upper edge (B), form an angle δ less than 70° , especially less than 65 or 60° , preferably of about 40° .

18. (Amended) Prosthesis according to claim 1, characterized in that the planes P7 and P8 tangent to the anterior surface (52) and to the posterior surface (51), respectively, of the pouch (2), once it is filled and in the implantation position at the inner edge (C), form an angle β less than 65° , especially less than 60° , for example on the order of 40° .

19. (Amended) Prosthesis according to claim 1, characterized in that it is based on elastomer(s) of the silicone type.

20. (Amended) Prosthesis according to claim 1, characterized in that the pouch is filled with the filling material before and/or during and/or after the surgical implantation.

21. (Amended) Prosthesis according to claim 1, characterized in that this is an

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expansion prosthesis.

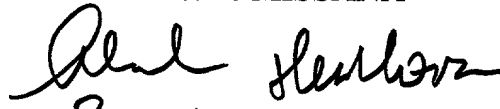
Remarks

Entry of this amendment is respectfully requested prior to examination of the application and calculation of filing fees. This Amendment is being filed in order to submit an Abstract of the Disclosure and to remove multiple claim dependencies.

The Commissioner is hereby authorized to refund excess fees and charge any fees necessary for the consideration of this preliminary amendment to Deposit Account No. 19-0089.

Should the Examiner have any further comments or questions, the Examiner is invited to contact the undersigned at the below-listed telephone number.

Respectfully submitted,
Marie-Christine MISSANA



Reg. No. 45,294

Neil F. Greenblum
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November 30, 2001
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Enclosures: Appendix 1
Appendix 2

APPENDIX 1

--ABSTRACT OF THE DISCLOSURE

Implantable breast prosthesis comprising a soft pouch capable of containing a filler substance such as a physiological serum or a silicone gel which is made side-specific, so as to satisfy aesthetic requirements and for better matching the convexity of the thorax.--

APPENDIX 2

CLAIMS

5. (Amended) Prosthesis according to [one of claims 3 or 4] claim 3, characterized in that, along the plane P2, the dimension of the projection along the plane EC of the distance between the nipple (E) and the inner edge (C) and the dimension of the projection EA' of the distance between said nipple (E) and the rear outer edge A' are equal or very close.

6. (Amended) Prosthesis according to [one of claims 3-5] claim 3, characterized in that, along the plane P2, the dimension of the projection of the distance BE between the upper edge B and the nipple E is greater than the dimension of the projection of the distance ED between the nipple E and the lower edge D.

8. (Amended) Prosthesis according to [one of the preceding claims] claim 1, characterized in that, once filled and in the implantation position, the pouch (2) has an outer overlap (44) with respect to its posterior surface (51), extending especially between the lower (D) and the upper (B) posterior edges.

9. (Amended) Prosthesis according to [one of the preceding claims] claim 1, characterized in that the plane P5 tangent at the rear outer edge k to the anterior surface 52 forms, together with the plane P6 at said point k to the posterior surface 51, an obtuse angle ϕ , especially greater than 95 or 100°, especially comprised between 91° and 120°, for example on the order of 115°.

10. (Amended) Prosthesis according to [one of the preceding claims] claim 1, characterized in that the posterior surface (51) of the pouch (2) in the implantation position at least partially has at least one concave curvature.

13. (Amended) Prosthesis according to [one of claims 10 or 11] claim 10, characterized in that the posterior surface (51) of the pouch (2) in the implantation position has a concave curvature in a vertical plane P9 passing especially by the upper edge (B).

15. (Amended) Prosthesis according to [one of the preceding claims] claim 1,

characterized in that the projection of the distance HI between the pole H of the posterior surface (51) and the pole I of the anterior surface (52) along a vertical plane and passing by the upper B and lower D edges is comprised between 3 and 7 centimeters, and is here on the order of 5 centimeters.

16. (Amended) Prosthesis according to [one of the preceding claims] claim 1, characterized in that at least a portion of the posterior surface (51) of the pouch (2) is less deformable or more rigid than the remainder of the pouch (2), especially by selective thickening of said posterior surface.

17. (Amended) Prosthesis according to [one of the preceding claims] claim 1, characterized in that the planes P10 and P11 tangent to the posterior surface (51) and to the anterior surface (52), respectively, of the pouch (2), once it is filled and in the implantation position at the upper edge (B), form an angle δ less than 70° , especially less than 65° or 60° , preferably of about 40° .

18. (Amended) Prosthesis according to [one of the preceding claims] claim 1, characterized in that the planes P7 and P8 tangent to the anterior surface (52) and to the posterior surface (51), respectively, of the pouch (2), once it is filled and in the implantation position at the inner edge (C), form an angle β less than 65° , especially less than 60° , for example on the order of 40° .

19. (Amended) Prosthesis according to [one of the preceding claims] claim 1, characterized in that it is based on elastomer(s) of the silicone type.

20. (Amended) Prosthesis according to [one of the preceding claims] claim 1, characterized in that the pouch is filled with the filling material before and/or during and/or after the surgical implantation.

21. (Amended) Prosthesis according to [one of the preceding claims] claim 1, characterized in that this is an expansion prosthesis.

Applicant or Patentee: _____ Attorney's
Serial or Patent No.: not yet assigned Docket No.: _____
Filed or Issued: concurrently herewith
For: Breast prosthesis

VERIFIED STATEMENT (DECLARATION) CLAIMING SMALL ENTITY
STATUS (37 CFR 1.9(f) and 1.27(b)) - INDEPENDENT INVENTOR

As a below named inventor, I hereby declare that I qualify as an independent inventor as defined in 37 CFR 1.9(c) for purposes of paying reduced fees under section 41(a) and (b) of Title 35, United States Code, to the Patent and Trademark Office with regard to the invention entitled _____ described in

- ☒ the specification filed herewith
☐ application serial no. _____, filed _____
☐ patent no. _____, issued _____

I have not assigned, granted, conveyed or licensed and am under no obligation under contract or law to assign, grant, convey or license, any rights in the invention to any person who could not be classified as an independent inventor under 37 CFR 1.9(c) if that person had made the invention, or to any concern which would not qualify as a small business concern under 37 CFR 1.9(d) or a nonprofit organization under 37 CFR 1.9(e).

Each person, concern or organization to which I have assigned, granted, conveyed, or licensed or am under an obligation under contract or law to assign, grant, convey, or license any rights in the invention is listed below:

- ☒ no such person, concern, or organization
☐ persons, concerns or organizations listed below*

*NOTE: Separate verified statements are required from each named person, concern or organization having rights to the invention averring to their status as small entities. (37 CFR 1.27)

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FULL NAME _____
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I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 CFR 1.28(b))

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

Marie-Christine MISSANA Arnaud ROCHEBILIERRE
NAME OF INVENTOR NAME OF INVENTOR NAME OF INVENTOR

Signature of Inventor Signature of Inventor Signature of Inventor
Date 6 5 October 2001 Date 5 October 2001 Date

BREAST PROSTHESIS

The invention relates to an implantable breast prosthesis adapted more particularly to breast augmentation surgery and breast reconstructive surgery.

5 Breast prostheses are generally constituted of a silicone-type elastomeric soft pouch which is filled with a more or less viscous fluid. In Europe, this fluid most often is a physiological serum-base fluid which is inserted into the pouch during implantation of the prosthesis through an appropriate opening in the pouch which is sealed after the filling. In the United States, in particular, silicone gels are also used, inserted into the pouch which is
10 then sealed before implantation. A particular type of prosthesis is called an expander: these prostheses are implanted beneath the area of the tissues to be expanded, then are progressively filled by an appropriate valve system with a fluid such as a physiological serum. Several examples of embodiment of these conventional or expansion prostheses are found in the Patent Applications FR-2 735 354, FR-2 726 173, and FR-2 677 539.

15 Numerous prostheses are currently commercially available, these prostheses having so-called "high profile," "low profile", or "anatomical" round shapes. All of them attempt as close an approximation to the natural shape of the breast as possible, but none has fully succeeded. The round-shaped prostheses do not feel natural, are overly projecting in the upper and inner parts (in a known fashion, the volume of the breast, as well as that of the
20 prosthesis can be resolved into four parts depending upon their position in relation to the bust). With respect to the so-called anatomical shape, they have a more adapted shape, but they can easily be positioned incorrectly within the surgical pocket, because their posterior surfaces (i.e., the area of the prosthesis to be placed in contact with the thorax, which is also called the placement) have an inadequate contact with the thorax.

25 An object of the present invention is an improvement to the design of breast prostheses, this improvement aiming particularly at a more aesthetic aspect, which is closer to that of the natural breast, regardless of whether the person wearing the prosthesis is seating, standing, or laying down, and/or a greater ease in positioning the prosthesis correctly during implantation, and/or a more constant retention of the prosthesis once it is
30 implanted in the correct position, and/or a greater comfort in wearing the prosthesis.

A primary object of the invention is a breast prosthesis comprising a soft pouch capable of containing a sufficiently fluid filling material, such as a silicone or hydrocolloid gel or a physiological serum, said prosthesis being made side-specific.

In the context of the invention, "made side-specific" means that, once filled, the

pouch demarcates a volume that cannot be placed indifferently to the left or to the right on the person's thorax: therefore, one obtains a right prosthesis and a left prosthesis, which are as specific as the natural breasts, especially with respect to the geometry of the posterior surface of the pouch and/or that of the anterior surface thereof ("anterior", as opposed to "posterior," designates the surface created by the pouch turned to the side opposite the thorax).

In addition to this side-specific arrangement translating into differences in the geometry between the (lower and upper) outer parts, on the one hand, and the (lower and upper) inner parts on the other hand, one can advantageously provide an additional side-specific arrangement translating into differences in the geometry between the (inner and outer) lower parts, on the one hand, and the (inner and outer) upper parts on the other hand: thus, one can also distinguish, in each prosthesis of the invention, the "upper" portion and the "lower" portion, in the implantation position, which cannot be inverted.

In the context of the invention, a "pouch capable of containing" means either the complete prosthesis, with the pouch fully filled with the filling fluid, or the partially filled pouch, or yet the pouch still empty since, as mentioned hereinabove, the prostheses, depending particularly on the type of filling fluid selected or the function of the prosthesis, are in the form of empty or pre-filled pouches before implantation. Preferably, it is a final prosthesis. Since the geometry of the pouch determines that of the prosthesis as a whole, once the pouch is filled, the invention is more clearly defined with reference to a filled pouch defining the volume approximating that of the breast.

Indeed, the inventors became aware that such a "side-specific arrangement", such an asymmetry was the solution to the problem of overcoming the disadvantages of the prostheses currently used.

This side-specific arrangement can be obtained at various levels, which can be alternative, or preferably cumulative.

Thus, a first level is the choice of an asymmetry of the pouch in the implantation position (for ease of understanding, the implantation position is that of a person standing or sitting with her bust straight), once filled, in relation to a plane P1 passing by the nipple E (the front pole of the anterior surface simulating the breast nipple) and by the lower D and upper B front edges. Thus, this characteristic takes into account the asymmetry of the breasts in relation to a vertical sagittal plane. Indeed, a natural breast is hemispherical only on a teenager. Subsequently, it spreads on the thorax wall and then progressively displays a more rounded and more protruding aspect in the lower and outer parts. The asymmetry

according to the invention advantageously enables the volume of the lower outer part of the implanted prosthesis to be larger than that of the lower inner part and/or that of the upper outer part to be larger than that of the upper inner part.

Preferably, this asymmetry is defined by a difference in the dimensions between the
 5 projection of the distance EC between the nipple and the front inner edge, on the one hand, and the projection of the distance EA between said nipple and the front outer edge, on the other hand, the projections being made along a plane P2 perpendicular to the plane P1 passing by the aforementioned nipple and containing said nipple E as well as the front upper edge B. The ratio between these two projections is advantageously less than or equal to
 10 0.95, especially comprised between 0.8 and 0.9, or between 0.85 and 0.90. The preferred embodiment consists of selecting a ratio on the order of 0.875, which is that most capable of reproducing the more outwardly projecting aspect of the natural breast, whereas the currently available prostheses have a ratio strictly equal to 1.

Conversely, it is preferable that the projection of the distance EC between the nipple
 15 E and the inner edge C be equal to or very close to the projection of the distance EA' between the nipple E and the rear outer edge A', along this same plane P2: this configuration especially allows obtaining an outer "overlap" of the filled pouch in the implantation position in relation to the posterior surface thereof, this overlap extending in particular between the lower D and upper B rear edges, which simulates the aspect of the natural breast
 20 at best.

Advantageously, the prosthesis is designed such that, along the plane P2 described hereinabove, the dimension of the projection of the distance BE between the upper edge B and the nipple E is greater than the dimension of the projection of the distance ED between the nipple and the lower edge D. The ratio r (BE/ED) is preferably at least 1.1, especially
 25 between 1.1 and 2, or between 1.3 and 1.5.

Incidentally, to obtain the aforementioned "outward" overlapping effect, it is advantageous to have the plane P5 tangent, at k (the rear outer edge) to the anterior surface of the prosthesis form, at k, with the plane P6 tangent, at said point k, to the posterior surface, an obtuse angle ϕ , especially greater than 95 or 100°, in particular comprised
 30 between 91° and 120°, for example on the order of 115°.

Preferably, the prosthesis does not contain any axillary extension or the like.

A second level of side-specific arrangement relates to taking into account the natural convexity of the thorax in a horizontal plane (still with the understanding that the prosthesis is filled and in the implantation position). The current prostheses have a planar posterior

surface. The incorrect positions, prosthetic rotations and aesthetic drawbacks observed after implantation are explained in particular by this choice: since the prostheses assume the shape of the thoracic plane only on an insufficient surface, they can easily move. Conversely, according to the invention, at least one concave curvature is preferably imparted to the posterior surface, in order to increase this contact surface, and therefore to improve the fit of the prosthesis on the thorax.

Advantageously, a first concave curvature is provided in a horizontal plane P3, this plane passing by the inner edge C, for example. In this case, the perpendicular projection GG' of the pole G of the posterior surface on the horizontal plane P4 containing the outer rear edge A' and the inner edge C, is at least 3 mm, especially at least 5 mm or 1 cm, for example 0.8 - 1.5 cm.

Still advantageously, the posterior surface can also have a concave curvature, in a vertical plane P9, this time, this vertical plane passing by the upper edge B, for example. In this case, the perpendicular projection HH' of the pole H of the posterior surface along this curvature on a vertical plane P10, perpendicular to P9 and passing by the upper edge B, is at least 2 mm, especially comprised between 3 and 6 mm.

It is with this double curvature that the posterior surface closely fits the curvature of the thorax at best. Advantageously, the first curvature is uninterrupted between the inner edge C and the outer rear edge A', and similarly, the second curvature is uninterrupted from the upper edge B to the rear lower edge D (i.e., with no inverted planar or curvature zone between the two points considered for each of the curvatures).

To obtain this non-planar posterior surface, it can be made more rigid, less deformable than the anterior surface, for example by selectively increasing the thickness of the wall of this surface.

A third level of side-specific arrangement relates to the "connection" zones between the prosthesis and the thorax: the completely symmetrical prostheses currently available generally do not take into account either that the natural breasts, especially in the inner zone and in the upper zone, connect to the thorax along a "gentle" slope and not in a quasi-perpendicular manner with respect to the thorax.

Conversely, according to the invention, one first provides to simulate this gentle slope connection in the upper zone of the prosthesis, by designing the prosthesis such that the planes P10 and P11 tangent to the posterior surface and to the anterior surface, respectively, of the pouch, once it is filled and in the implantation position at the upper edge B, form therebetween an angle less than or equal to 70° , especially less than or equal to 65° .

or 60°, for example on the order of 40°.

Alternatively or cumulatively, the invention also provides a gentle slope connection of the prosthesis with the thorax in the inner zone of the prosthesis: the pouch is designed such that the planes P7 and P8 tangent to the anterior surface and to the posterior surface, respectively, of the pouch, once it is filled and in the implantation position at the inner edge C, form therebetween an angle less than or equal to 70°, especially less than or equal to 65 or 60°, for example on the order of 40°.

The object of the invention concerns the prostheses having at least one level of side-specific arrangement and pertaining to the family of prostheses defined in the preamble of the present application. It relates to prostheses having all of the volumes commonly used in breast surgery, namely, prostheses which, once filled, have a volume ranging from 80 cm³ to 700 cm³.

The details and advantageous characteristics of the invention will now become apparent from the following non-limiting example, by means of Figures 1-6:

- Figure 1 schematically shows a transverse cross-section of a thorax with natural breasts.
- Figure 2 shows the same cross-section with two prostheses according to the prior art.
- Figure 3 shows the same cross-section with two prostheses according to the invention.
- Figure 4 shows a view of the anterior surface along a vertical plane of the right prosthesis according to the invention.
- Figure 5 shows a view of the prosthesis of Figure 4 in a horizontal cross-section.
- Figure 6 shows a side view of the prosthesis of Figure 4.

Therefore, Figure 1 is a transverse cross-section of the thorax in a mediastinal window passing by the fourth dorsal vertebra, schematically shown from a scannographic illustration. One sees the spine 10, the two breasts 11 and 12, the mediastinum 13, the lung fields 14 and 15, the costal plane 16. It can be noted that the two breasts “spread” naturally on the thoracic plane 16 by assuming its convex shape. The arrows represent the inner and outer limits of the projection of the two areolar glands on the thorax.

Figure 2 shows, along the same cross-section as in Figure 1, some of the drawbacks of one type of (comparative) prosthesis that is currently commercially available: the prostheses 21 and 22 have planar posterior surfaces 23 and 24 which do not follow the curvature of the thorax. In addition, they create, in the inner zones 25 and 26 for connection with the thorax, an almost 90° angle with said thorax. And we are almost in the same

situation in the outer connection zones 27 and 28: the external appearance of the prosthesis is therefore anaesthetic, on the one hand, and it is susceptible of moving in the pocket where it is implanted, increasing the anaesthetic effect and the discomfort for the person, on the other hand.

5 Figure 3 shows the prostheses 31, 32 according to a preferred embodiment of the invention: they are much closer to the aspect of the breasts of Figure 1, with a posterior surface 33, 34 assuming the convexity of the thorax as closely as possible, and connections in inner zones 35, 36 and in outer zones 37, 38 along a gentle slope. The prostheses 31, 32 have a volume that is better distributed and closer to the thoracic cage; as a result, they are
10 much less susceptible of moving. It is also seen that the prostheses 31, 32, contrary to the prostheses 21, 22, are not interchangeable. They are made side-specific, asymmetrical as are the natural breasts.

The following Figures will discuss the geometry of the prosthesis 31 in detail.

15 Figure 4 therefore shows a front view of the right prosthesis 31 of Figure 3. It is understood that from this representation, as well as all of the following ones, can derive those of the left breast, which is the mirror construction in volume of the right prosthesis. This representation and the following ones are on a scale of 1.

20 The point E shown is the front pole of the prosthesis, which corresponds to the nipple of the natural breast, the point C is the inner edge (that which is going to be turned toward the other prosthesis in the implantation position), the points B and D are the upper and lower front edges, respectively, the point A is the front outer edge (as opposed to "inner"), the point A' is the rear outer edge and the point D' the rear lower edge. This is a prosthesis having a volume of about 480 cm³.

25 The dimensions of the distances between these various points, measured in the plan P2, are as follows:

AA' = 1 cm (length of the outer overlap)

A'C = 14 cm (base of the prosthesis)

AC = 15 cm (total width of the prosthesis)

BD = 12 cm (total height of the prosthesis)

30 DD' = 2 mm

A'E = EC = 7 cm

AE = 8 cm

BE = 7 cm

ED = 5 cm

It is seen that the prosthesis does not have any symmetry in relation to the plane P1 passing by B, D, and E, and perpendicular to the plane P2 represented in the Figure: the distance EC is notably shorter than the distance AE, and the volumes of the upper 40 and lower 42 outer parts are larger than that of the volumes of the upper 41 and lower 43 inner parts. There is a hatched area 44 that corresponds to an overlap of the anterior surface in relation to the surface developed by the posterior surface, which translates into the distance separating the points A and A'. This overlap is most substantial in the vicinity of the points A and A', but it is seen that it extends up into the inner lower part 43 (the distance between D and D' is not negligible). The prosthesis also has an asymmetry between the volumes of the lower 42 and upper 40 outer parts, on the one hand, and between the volumes of the lower 43 and upper 41 inner parts, on the other hand, which translates into the difference between the distances BE and ED. In the present case, the ratio r (BE/ED) is 1.4. This ratio can be generally selected preferably between 1.1 and 2, especially between 1.3 and 1.5.

Figure 5 is a horizontal cross-sectional view of the previous Figure. According to this cross-section, the point F is the pole of the anterior surface 52 and G the pole of the posterior surface 51. G' is the projection of G in the plane P4 which is the plane perpendicular to the plane of the cross-section, and which passes by k and C. It must be noted that the axes BD of Figure 4 and FG of this Figure are perpendicular to one another, but with an offcentering of about 1 cm. They do not intersect.

The distances between these various points are:

$$GG' = 1.3 \text{ cm}$$

$$FG = 5 \text{ cm (front projection of the prosthesis)}$$

$$kG' = 6 \text{ cm}$$

$$GC = 8 \text{ cm}$$

Therefore, one easily sees that the posterior surface 51 has a uniform concavity extending between the points k and C. This concavity can be quantified by the distance GG' which is greater than 1 cm, and by the angles α formed by the planes tangent to the posterior surface 51, at points k and C, with the plane P4. Here, the two angles on the outer and inner side are substantially identical (about 25° , which can be comprised between 20° and 30°), but it could be otherwise. It can be noted that G' is not in the middle of kC. There is an A'G/G'C ratio of about 0.75 (for example comprised between 0.5 and 1). The hatched area 53 corresponds to the outer overlap designated by the reference numeral 44 in the previous Figure; it makes it possible to see more clearly that the prosthesis allows obtaining the natural effect of an outwardly projecting breast.

Figure 5 also makes it possible to show a gentle slope connection mentioned hereinabove, the connection between the inner edge C of the prosthesis and the thorax: thus, the plane tangent to the posterior surface 51 at point C forms, together with the plane tangent to the anterior surface at same point C, a small angle β , much less than 90° , here on the order of 40° .

Figure 5 also shows that the outer overlap also translates into an angle ϕ of about 115° , at k, between the plane P5 passing by k and tangent to the anterior surface 52 and the plane P6 also passing by k and tangent to the posterior surface 51 of the prosthesis.

Figure 6 is a side view of the prosthesis 31. The point I is the pole of the anterior surface 52 along the plane of the Figure. The point H is the pole of the posterior surface 51 along the plane of the Figure. The point H' is the perpendicular projection of H on a vertical plane P9 passing by B and perpendicular to the plane of the Figure. The distances between these various points are as follows:

$$HH' = 3.5 \text{ mm}$$

$$HI = 5 \text{ cm (front projection of the prosthesis)}$$

$$HD = 5 \text{ cm}$$

$$H'B = 7 \text{ cm}$$

$$DD' = 2 \text{ mm}$$

The posterior surface 51 has a second concavity in the plane of the Figure. This concavity can be quantified by the distance HH' which is greater than 1 mm, and by the angles χ formed by the plane tangent to the posterior surface 51 at point B with the plane P9. (The situation is the same at point D', the concavity extending from B up to D'). Here, the angle χ is about 7° , and can be comprised between 4° and 15° , for example.

Figure 6 also makes it possible to see a second gentle slope connection on the upper zone of the prosthesis: at point B, the angle δ formed by the plane P10 explained hereinabove and the plane P11 tangent to the anterior surface to point B is small, much less than 90° or 60° , and it is selected here to be about 38.5° .

The distance HI is an important characteristic of the prosthesis because it makes it possible to define the front projection of the prosthesis. In this specific example, it is 5 centimeters, but it can be selected more generally in a range of 3-7 centimeters.

In conclusion, this non-limiting example of prosthesis is the one that combines all of the characteristics of the invention for even closer an approximation to the aspect of the natural breast than before. Prostheses of various volumes can result from mere similarity. However, it remains consistent with the invention to provide prostheses that would not

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cumulate all of the means for side-specific arrangement, (adaptation to the convexity of the thorax by a concave posterior surface and/or at least one “gentle slope connection”, and/or an asymmetry in relation to a vertical plane passing by the nipple, and/or an outer “overlap”...).

CLAIMS

1. Implantable breast prosthesis (1) comprising a soft pouch (2) capable of containing a filling material (3) such as a silicone gel or a physiological serum,
 5 **characterized in that** said prosthesis (1) is made side-specific, and **in that** the planes P7 and P8 tangent to the anterior surface (52) and to the posterior surface (51), respectively, of the pouch (2), once it is filled and in the implantation position at the inner edge (C), form an angle β less than 70° .

2. Prosthesis according to claim 1, **characterized in that** the side-specific
 10 arrangement of the prosthesis is obtained by an asymmetry of the pouch (2) in the implantation position, once it is filled, in relation to a plane P1 passing by the nipple (E) and the lower (D) and upper (B) front edges.

3. Prosthesis according to claim 2, **characterized in that** the asymmetry is defined by a difference in the dimensions between the projection EC of the distance between
 15 the nipple (E) and the front inner edge (C), on the one hand, and the projection EA of the distance between said nipple (E) and the front outer edge (A), on the other hand, along a plane P2 perpendicular to the plane P1 and containing the nipple (E) and the front upper edge B.

4. Prosthesis according to claim 3, **characterized in that** the ratio $r(EC/EA)$ of
 20 said projections is less than or equal to 0.95, especially comprised between 0.8 and 0.9, or between 0.85 and 0.90, preferably equal to about 0.875.

5. Prosthesis according to one of claims 3 or 4, **characterized in that**, along the plane P2, the dimension of the projection along the plane EC of the distance between the
 25 nipple (E) and the inner edge (C) and the dimension of the projection EA' of the distance between said nipple (E) and the rear outer edge A' are equal or very close.

6. Prosthesis according to one of claims 3-5, **characterized in that**, along the plane P2, the dimension of the projection of the distance BE between the upper edge B and the nipple E is greater than the dimension of the projection of the distance ED between the
 nipple E and the lower edge D.

7. Prosthesis according to claim 6, **characterized in that** the ratio $r(BD/ED)$ is
 30 at least 1.1, especially between 1.1 and 2, and preferably between 1.3 and 1.5.

8. Prosthesis according to one of the preceding claims, **characterized in that**, once filled and in the implantation position, the pouch (2) has an outer overlap (44) with respect to its posterior surface (51), extending especially between the lower (D) and the

upper (B) posterior edges.

9. Prosthesis according to one of the preceding claims, *characterized in that* the plane P5 tangent at the rear outer edge k to the anterior surface 52 forms, together with the plane P6 at said point k to the posterior surface 51, an obtuse angle ϕ , especially greater than
5 95 or 100°, especially comprised between 91° and 120°, for example on the order of 115°.

10. Prosthesis according to one of the preceding claims, *characterized in that* the posterior surface (51) of the pouch (2) in the implantation position at least partially has at least one concave curvature.

11. Prosthesis according to claim 10, *characterized in that* the posterior surface
10 (51) of the pouch (2) in the implantation position has a concave curvature in a horizontal plane P3 passing especially by the inner edge (C).

12. Prosthesis according to claim 11, *characterized in that* the projection GG' of the pole (G) of the posterior surface (51) along the concave curvature in a horizontal plane on the horizontal plane P4 containing the inner edge (C) and rear outer edge (A'), distance
15 measured perpendicular to said plane, is at least 5 mm, especially at least 1 cm.

13. Prosthesis according to one of claims 10 or 11, *characterized in that* the posterior surface (51) of the pouch (2) in the implantation position has a concave curvature in a vertical plane P9 passing especially by the upper edge (B).

14. Prosthesis according to claim 13, *characterized in that* the distance HH' between the pole (H) of the posterior surface (51) along the concave curvature in the vertical plane and the vertical plane P9 passing by the upper edge (B), distance measured perpendicular to said plane P9, is at least 1 mm, especially at least 2 mm, and preferably comprised between 3 and 6 mm.
20

15. Prosthesis according to one of the preceding claims, *characterized in that* the projection of the distance HI between the pole H of the posterior surface (51) and the pole I of the anterior surface (52) along a vertical plane and passing by the upper B and lower D edges is comprised between 3 and 7 centimeters, and is here on the order of 5 centimeters.
25

16. Prosthesis according to one of the preceding claims, *characterized in that* at least a portion of the posterior surface (51) of the pouch (2) is less deformable or more rigid than the remainder of the pouch (2), especially by selective thickening of said posterior surface.
30

17. Prosthesis according to one of the preceding claims, *characterized in that* the planes P10 and P11 tangent to the posterior surface (51) and to the anterior surface (52), respectively, of the pouch (2), once it is filled and in the implantation position at the upper

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edge (B), form an angle δ less than 70° , especially less than 65 or 60° , preferably of about 40° .

18. Prosthesis according to one of the preceding claims, *characterized in that* the planes P7 and P8 tangent to the anterior surface (52) and to the posterior surface (51), respectively, of the pouch (2), once it is filled and in the implantation position at the inner edge (C), form an angle β less than 65° , especially less than 60° , for example on the order of 40° .

19. Prosthesis according to one of the preceding claims, *characterized in that* it is based on elastomer(s) of the silicone type.

20. Prosthesis according to one of the preceding claims, *characterized in that* the pouch is filled with the filling material before and/or during and/or after the surgical implantation.

21. Prosthesis according to one of the preceding claims, *characterized in that* this is an expansion prosthesis.

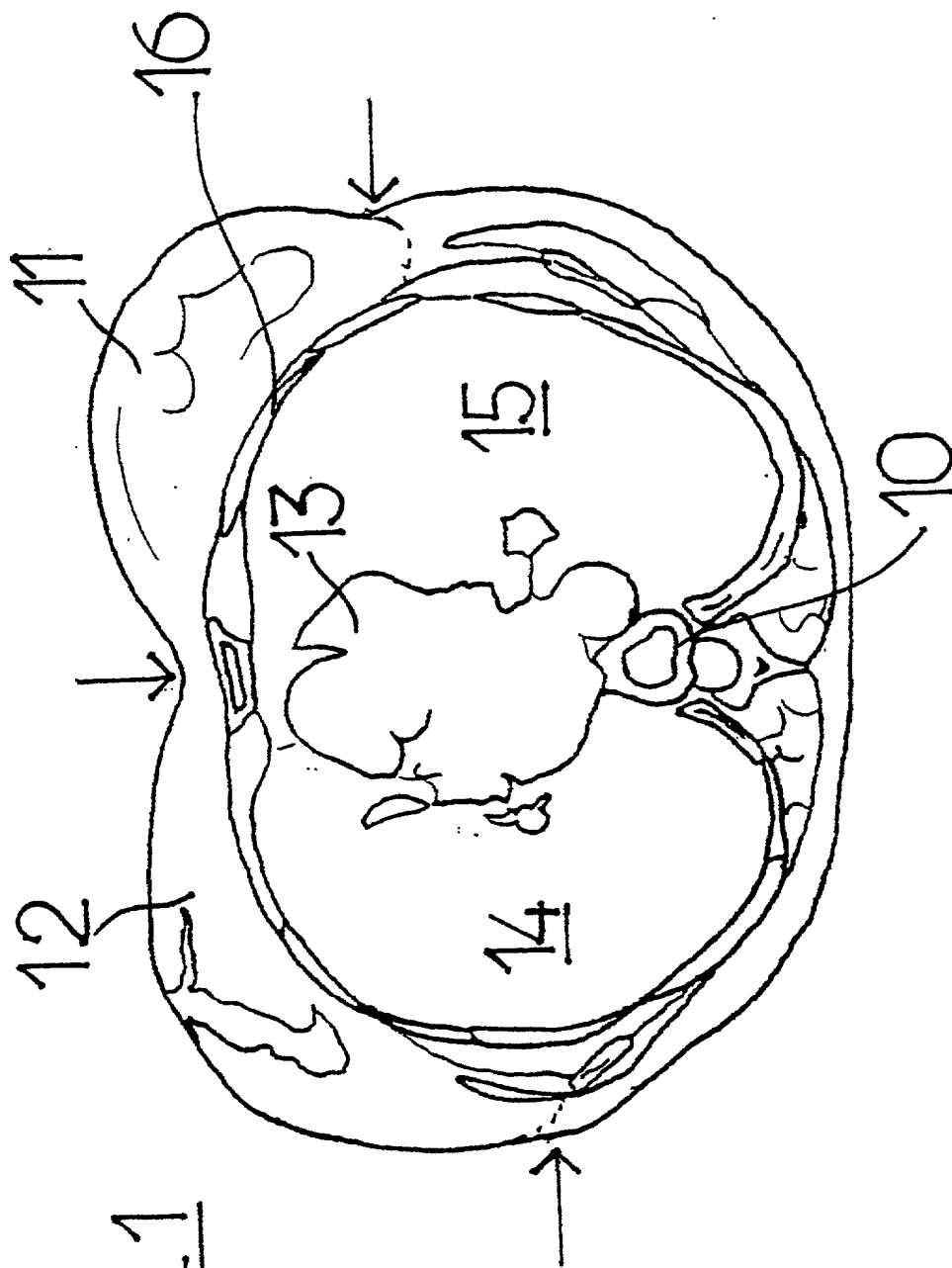


FIG. 1

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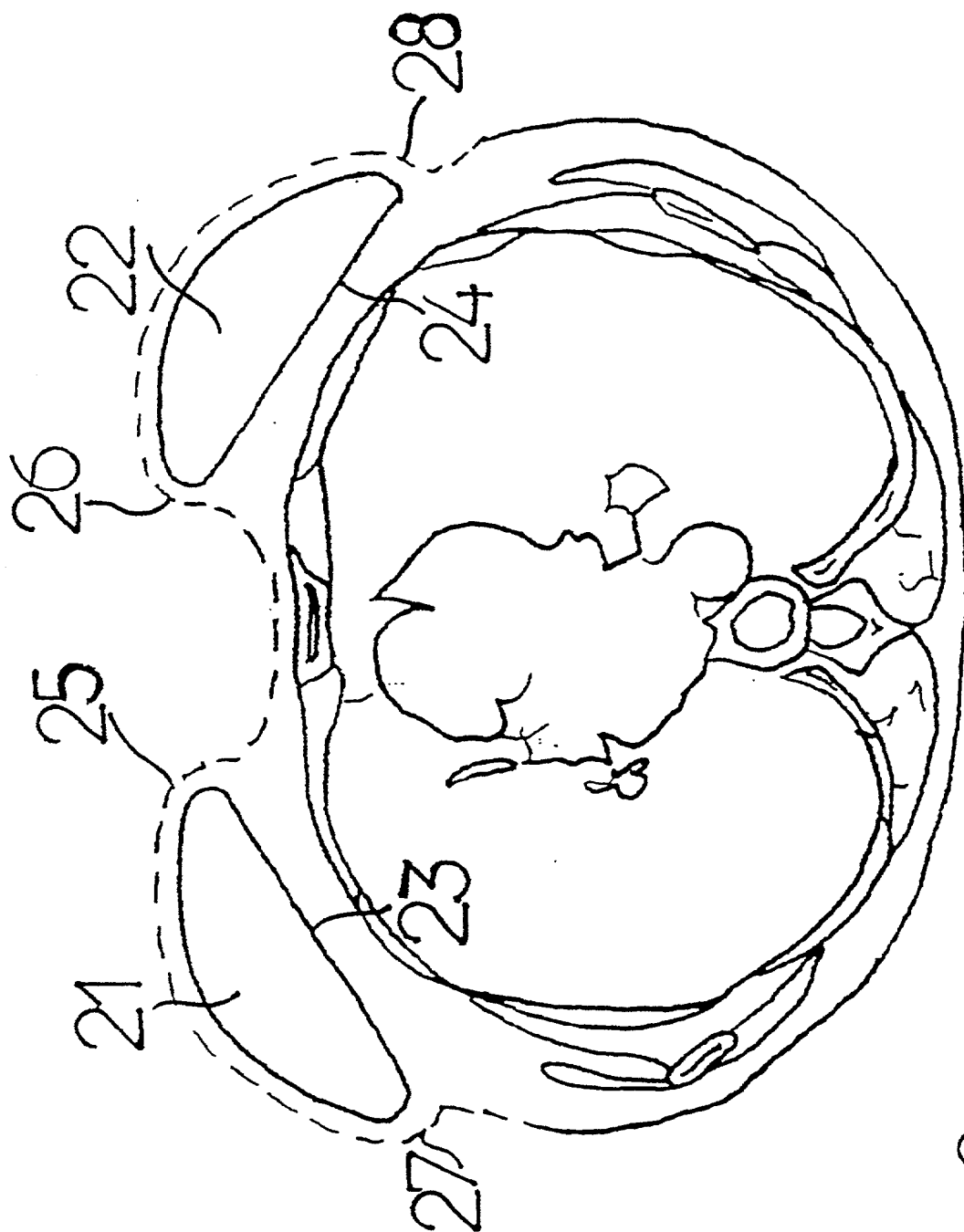


FIG. 2

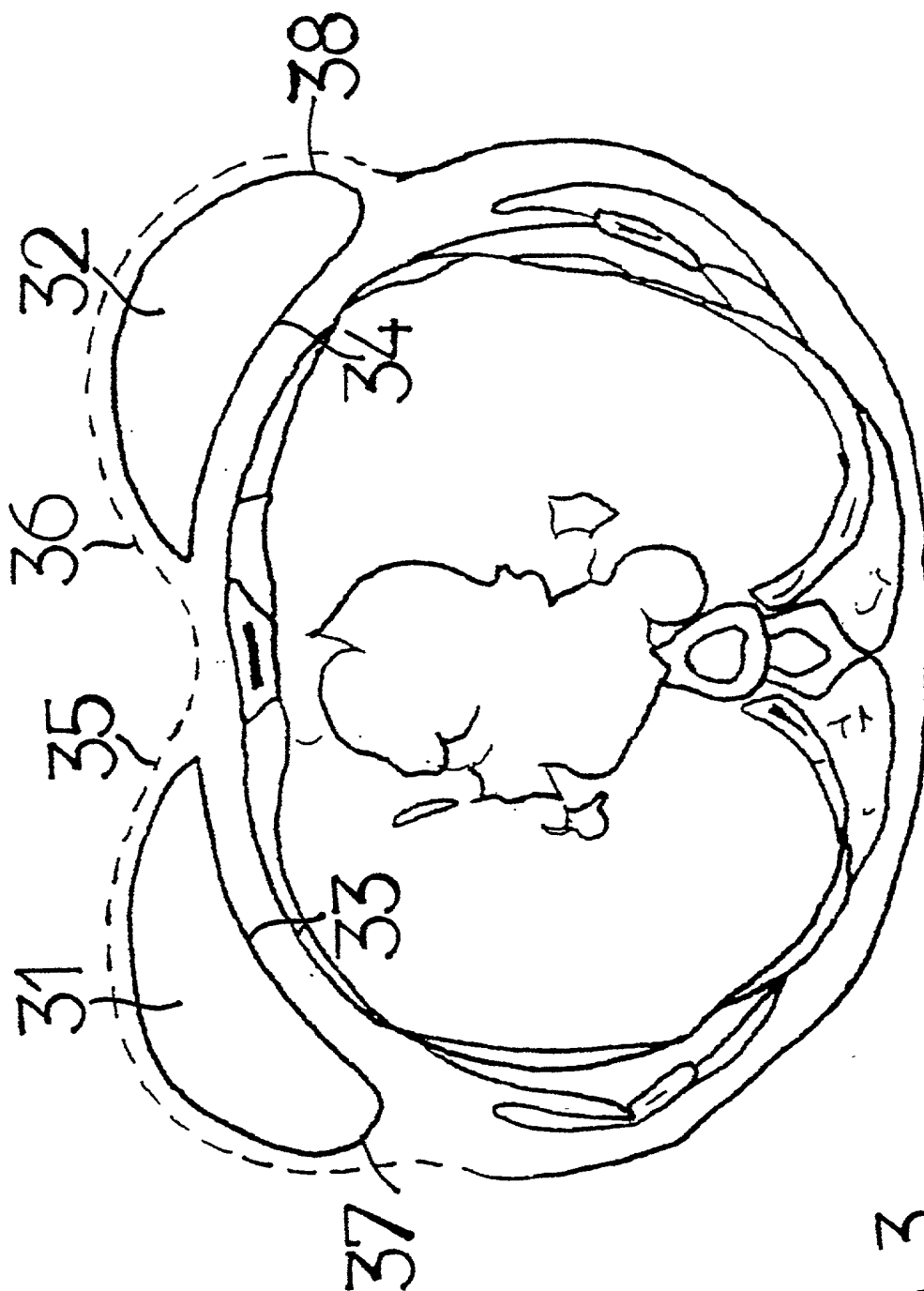


FIG. 3

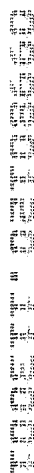
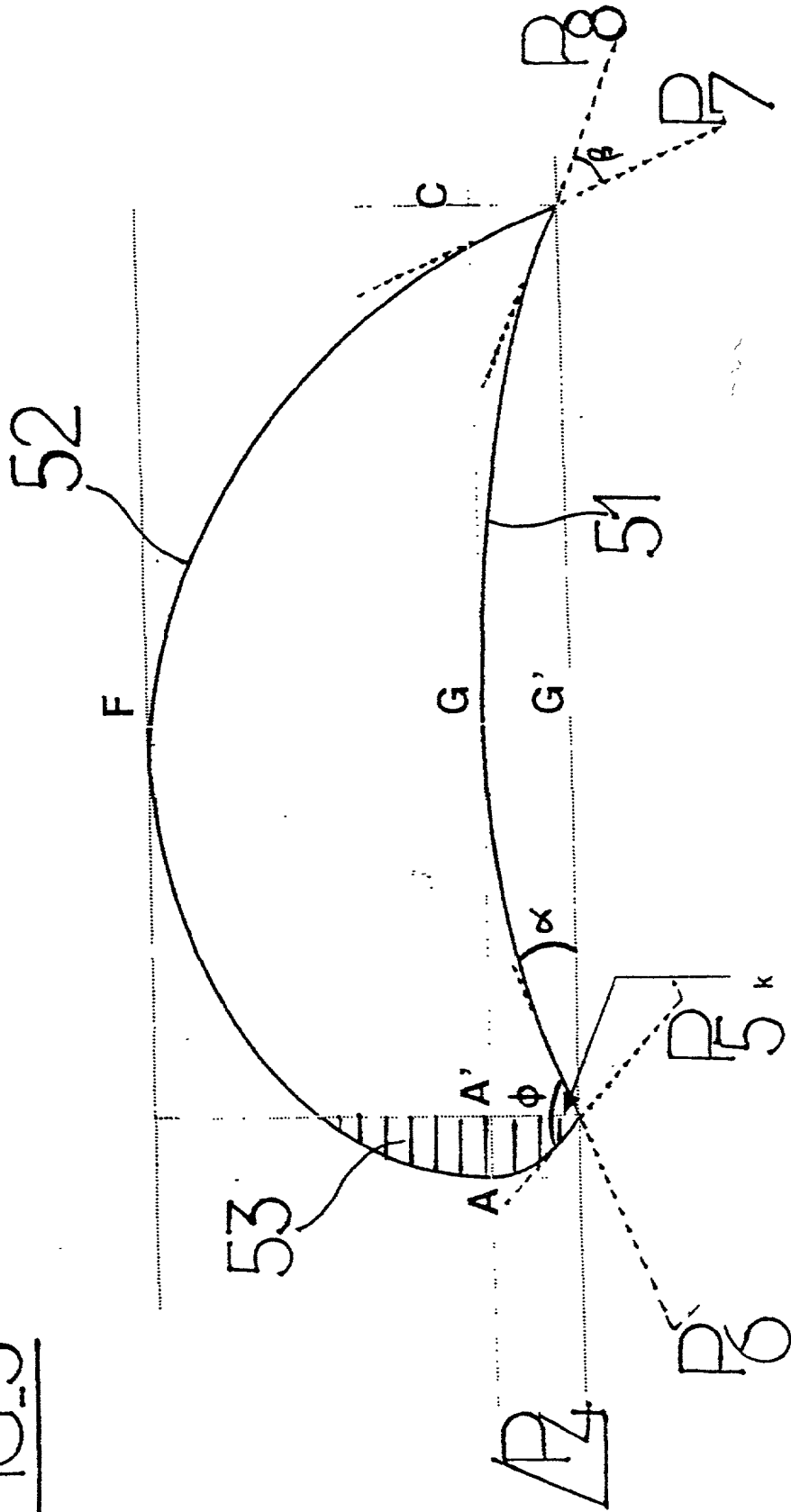


FIG. 4

FIG. 5



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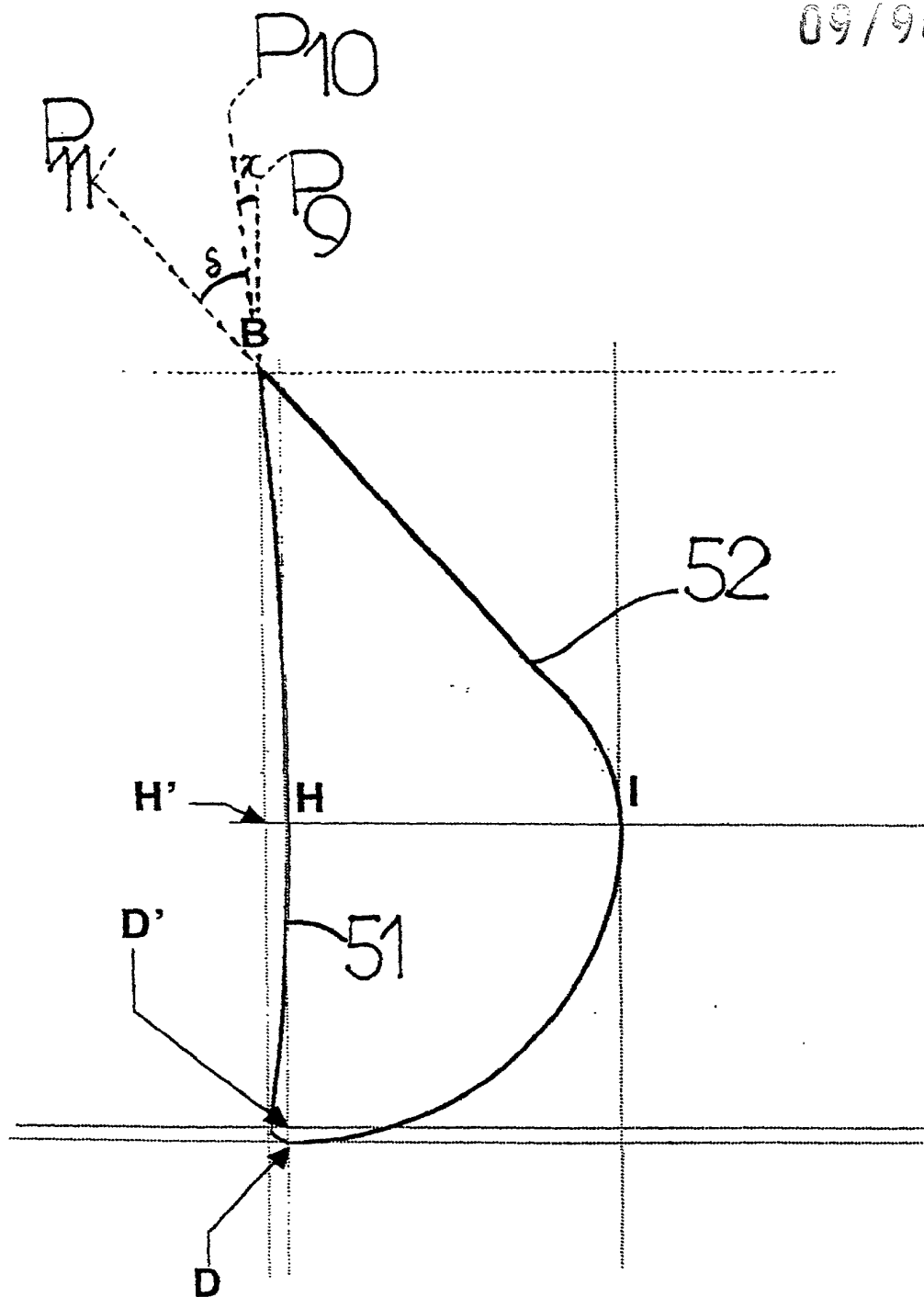


FIG. 6

Declaration and Power of Attorney For Utility or Design Patent Application

Déclaration pour Demandes de Brevet d'Utilité et de Modèle avec Pouvoirs

French Language Declaration

En tant qu'inventeur nommé ci-après, Je déclare par le présent acte que:

As a below named inventor, I hereby declare that.

Mon domicile, mon adresse postale et ma nationalité sont ceux figurant ci-dessous à côté de mon nom.

My residence, post office address and citizenship are as stated below next to my name.

Je crois être le premier inventeur original et unique (si un seul nom est mentionné ci-dessous), ou l'un des premiers co-inventeurs originaux (si plusieurs noms sont mentionnés ci-dessous) de l'objet revendiqué, pour lequel une demande de brevet a été déposée concernant l'invention intitulée
PROTHESE MAMMAIRE

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled

BREAST PROSTHESIS

La description dont la description est fournie ci-jointe à moins que la case suivante n'ait été cochée:

the specification of which is attached hereto unless the following box is checked:

■ a été déposée 29 mai 2000
sous le numéro de demande des Etats-Unis _____
et modifiée le _____ (le cas échéant)
ou,

■ was filed on May 29, 2000 as
United States Application Number _____
and was amended on _____ (if applicable)
or,

le numéro de demande internationale PCT PCT/FR00/01457
et modifiée le _____ (le cas échéant).

PCT International Application Number PCT/FR00/01457
and was amended on _____ (if applicable).

Je déclare par le présent acte avoir passé en revue et compris le contenu de la description ci-dessus, revendications comprises, telles que modifiées par toute modification dont il aura été fait référence ci-dessus.

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above.

Je reconnais devoir divulguer toute information pertinente à la brevetabilité, comme défini dans le Titre 37, § 1.56 du Code fédéral des réglementations.

I acknowledge the duty to disclose information which is material to patentability as defined in Title 37, Code of Federal Regulations, § 1.56.

Je revendique par le présent acte avoir la priorité étrangère, en vertu du Titre 35, § 119(a)-(d) ou § 365(b) du Code des Etats-Unis, sur toute demande étrangère de brevet ou certificat d'inventeur ou, en vertu du Titre 35, § 365(a) du même Code, sur toute demande internationale PCT désignant au moins un pays autre que les Etats-Unis et figurant ci-dessous. J'ai aussi indiqué ci-dessous, en cochant la case "Non", toute demande étrangère de brevet, tout certificat d'inventeur ou toute demande internationale PCT ayant une date de dépôt précédant celle de la demande à propos de laquelle une priorité est revendiquée.

I hereby claim foreign priority under Title 35, United States Code § 119 (a-d) or § 365(b) of any foreign application(s) for patent or inventor's certificate, or § 365(a) of any PCT international application which designated at least one country other than the United States, listed below. I have also identified below, by checking the "No" box, any foreign application for patent or inventor's certificate, or of any PCT international application having a filing date before that of the application on which priority is claimed:

Prior foreign applications
Demandes antérieures étrangères

Priority claimed
Priorité revendiquée

<u>99/06929</u>	<u>FRANCE</u>	<u>2/June/1999</u>
(Number)	(Country)	(Day/Month/Year Filed)
(Numéro)	(Pays)	(Jour/Mois/Année de dépôt)
_____	_____	_____
(Number)	(Country)	(Day/Month/Year Filed)
(Numéro)	(Pays)	(Jour/Mois/Année de dépôt)

■	□
Yes	No
Oui	Non
□	□
Yes	No
Oui	Non

□ D'autres demandes étrangères sont énumérées sur la feuille de priorité supplémentaire ci-jointe

□ Additional foreign application numbers are listed on a supplemental priority sheet attached hereto.

French Language Utility or Design Patent Application Declaration

Je revendique par le présent acte tout bénéfice, en vertu du Titre 35 §119(e) du Code des Etats-Unis, de toute demande de brevet provisoire effectuée aux Etats-Unis et figurant ci-dessous.

(Application No.)
(No. de la demande)

(Application No.)
(No. de la demande)

(Application No.)
(No. de la demande)

☐ D'autres demandes provisoires sont énumérées sur la feuille de priorité supplémentaire ci-jointe.

Je revendique par le présent acte tout bénéfice, en vertu du Titre 35, §120 du Code des Etats-Unis, de toute demande de brevet effectuée aux Etats-Unis, ou en vertu du Titre 35, §365 (c) du même Code, de toute demande internationale PCT désignant les Etats-Unis et figurant ci-dessous et, dans la mesure où l'objet de chacune des revendications de cette demande de brevet n'est pas divulgué dans la demande antérieure américaine ou internationale PCT, en vertu des dispositions du premier paragraphe du Titre 35, §112 du Code des Etats-Unis, je reconnais devoir divulguer toute information pertinente à la brevetabilité, comme défini dans le Titre 37, §1.56 du Code fédéral des réglementations, dont j'ai pu disposer entre la date de dépôt de la demande antérieure et la date de dépôt de la demande nationale ou internationale PCT de la présente demande:

(Application No.)
(No. de la demande)

(Day/Month/Year Filed)
(Jour/Mois/Année de dépôt)

(Application No.)
(No. de la demande)

(Day/Month/Year Filed)
(Jour/Mois/Année de dépôt)

☐ D'autres demandes américaines ou internationales sont énumérées sur la feuille de priorité supplémentaire ci-jointe.

Je déclare par le présent acte que toute déclaration ci-incluse est, à ma connaissance, véridique et que toute déclaration formulée à partir de renseignements ou de suppositions est tenue pour véridique; et de plus, que toutes ces déclarations ont été formulées en sachant que toute fausse déclaration volontaire ou son équivalent est passible d'une amende ou d'une incarcération, ou des deux, en vertu de la Section 1001 du Titre 18 du Code des Etats-Unis, et que de telles déclarations volontairement fausses risquent de compromettre la validité de la demande de brevet ou du brevet délivré à partir de celle-ci.

Le(s) soussigné(s) autorise(nt) par la présente le(s) avocat(s) américain(s) ou le(s) mandataire(s) ci-après désigné(s) à accepter et à suivre les instructions, soit de son(leurs) conseil(s) en brevet étranger(s), soit du représentant officiel de la société, concernant toute démarche nécessaire à effectuer auprès de l'Office américain des Brevets et des Marques concernant cette demande, sans communication directe entre le(s) avocat(s) américain(s) ou le(s) mandataire(s) nommé(s) par la présente sera(ont) informé(s) par le(s) soussigné(s). Dans l'hypothèse d'un changement dans les donneurs d'instructions, le(s) avocat(s) américain(s) ou le(s) mandataire(s) nommé(s) par la présente sera(ont) informé(s) par le(s) soussigné(s).

I hereby claim the benefit under Title 35, United States Code §119(e) of any United States provisional application(s) listed below.

(Day/Month/Year Filed)
(Jour/Mois/Année de dépôt)

(Day/Month/Year Filed)
(Jour/Mois/Année de dépôt)

(Day/Month/Year Filed)
(Jour/Mois/Année de dépôt)

☐ Additional provisional application numbers are listed on a supplemental priority sheet attached hereto.

I hereby claim the benefit under Title 35, United States Code §120 of any United States application(s), or §365(c) of any PCT international application designating the United States, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT international application in the manner provided by the first paragraph of Title 35, United States Code §112, I acknowledge the duty to disclose information which is material to patentability as defined in Title 37, Code of Federal Regulations §1.56 which became available between the filing date of the prior application and the national or PCT international filing date of this application.

(Status)
(Etat)
(patented, pending, abandoned)
(brevetée, pendante, abandonnée)

(Status)
(Etat)
(patented, pending, abandoned)
(brevetée, pendante, abandonnée)

☐ Additional U.S. or international application numbers are listed on a supplemental priority sheet attached hereto.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

The undersigned hereby authorizes the U.S. attorney or agent named herein to accept and follow instructions from either his foreign patent agent or corporate representative, if any, as to any action to be taken in the Patent and Trademark Office regarding this application without direct communication between the U.S. attorney or agent and the undersigned. In the event of a change in the persons from whom instructions may be taken, the U.S. attorney or agent named herein will be so notified by the undersigned.

French Language Utility or Design Patent Application Declaration

POUVOIR: En tant qu'inventeur, je désigne l'(les) avocat(s) et/ou l'(les) agent(s) associés au Numéro Client indiqué ci-dessous pour poursuivre la procédure de cette demande et traiter toute affaire la concernant auprès de l'Office des Brevets et des Marques, et autorise à ce que toute correspondance soit associée à ce Numéro Client.

POWER OF ATTORNEY: As a named inventor, I hereby appoint the attorney(s) and/or agent(s) associated with the Customer Number provided below to prosecute this application and transact all business in the Patent and Trademark Office connected therewith, and direct that all correspondence be addressed to that Customer Number:

NUMERO CLIENT 7055

CUSTOMER NUMBER 7055

Les avocats actuellement désignés sont énumérés ci-après:

The appointed attorneys presently include:

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 Bruce H. Bernstein Reg. No. 29,027
 Arnold Turk Reg. No. 33,094
 James L. Rowland Reg. No. 32,674


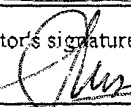
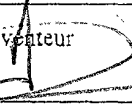
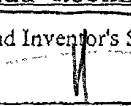
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FRANCE (Fournir les mêmes renseignements et la signature de tout co-inventeur supplémentaire).	FRANCE (Supply similar information and signature for third and subsequent joint inventors.)